

Appl. No. 09/831,462  
Atty. Docket No. 7943M  
Amtd. Dated December 2, 2004  
Reply to Office Action Dated September 10, 2004  
Customer Number 27752

### REMARKS

#### Claim Status

Claims 6, 16 and 17 are amended in response to the rejection of the claims under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as misdescriptive. The word "it" in Claims 6 and 16 is replaced by "a particle of said polymeric surface active agent" and in Claim 17 by "a particle of said polyphosphate". The word "mesh" is inserted after "0.1 mm".

It is believed these amendments do not involve any introduction of new matter. Consequently, entry of these amendments is believed to be in order and is respectfully requested. No additional claims fee is known to be due as a result of these amendments.

By these amendments, Claims 6-17 and 26 to 50 remain pending in the application.

#### Rejection Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph

The Office Action states that Claims 6, 16, and 17 are misdescriptive in reciting the word "it" and in not reciting the word "mesh" after "0.1 mm". The word "it" in the claims has been replaced by "a particle of said polymeric surface active agent" or by "a particle of said polyphosphate" accordingly. This amendment also provides antecedent basis for the word "it" in Claims 29 to 36 referring to a particle of polyphosphate. The word "mesh" has been inserted after "0.1 mm" thus making clear that the size refers to a mesh screen. Applicants are appreciative of the Examiner's suggestions to present the claims in better form. It is respectfully submitted that the claims as amended describe the claimed invention distinctly and definitely as required under the statute.

It is further submitted that the recitation of "up to about 10% of water" in Claims 6 and 16 is not indefinite as asserted in the Office Action. There is no requirement that the present compositions contain water. For example, none of the exemplified compositions have any added water. Any water present would only have been contributed by other ingredients such as sorbitol, which is normally supplied as an aqueous solution. If the compositions contained water, the amount should not be more than about 10%.

#### Claims Rejection Under 35 USC §103(a)

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**Claims Rejection Under 35 USC §103(a)**

Claims 6 to 17 and 26 to 50 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gaffar et al (US 4,808,401) in view of Chow et al. (US 5,833,954).

It is contended in the Office Action referring to the reasoning in the earlier Office Action of December, 2003 that coated chewing products are conventional and finding the optimum polyphosphate particle size, aqueous solubility, chain length and hardness would require nothing more than routine experimentation by one reasonably skilled in the art. Further, it is asserted that it would have been obvious to use the polyphosphate in the anticalculus chewing gum of Gaffar et al. at a particle size as presently claimed since it is well known as evidenced by Chow et al. to include phosphate salts having such particle size in dentifrices.

Applicants respectfully traverse the Examiner's rejection of the claims under 35 USC 35 U.S.C. §103(a) and submit that the claims as amended are unobvious in view of the cited art.

Firstly, Applicants believe it would be useful to briefly review the key features of the present invention and their attendant advantages. The present invention is directed to a chewing gum composition comprising a particulate polymeric surface active agent having specified properties, namely (i) a particle size such that it passes through a 2mm mesh and is retained by a 0.1mm mesh and (ii) an aqueous solubility of at least 5g per 100ml at 25°C. The particulate nature of the polymeric surface active agent coupled with the aqueous solubility properties provide the present chewing gum compositions with a crunchy texture which lasts during the initial minutes of chewing and disappears over time without leaving a gritty residue. The sensory experience during chewing provided by the texture and dissolution profile of the crunchy particulates are consumer noticeable and improve the acceptability of the chewing gum product by reinforcing to the consumer the oral care benefit of the product which includes surface conditioning effects to a subject's oral cavity surfaces perceived as improved cleaning and smooth feel of teeth.

Applicants respectfully submit that Gaffar et al. or Gaffar in combination with Chow et al. do not teach or suggest all of Applicants' claim limitations and therefore, do not

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establish a *prima facie* case of obviousness (see MPEP 2143.03). There is no disclosure or any suggestion whatsoever in Gaffar et al. or in Chow et al. to formulate chewing gum products with particulate polymeric surface active agents having the specified particle size and aqueous solubility in order to provide consumer-noticeable and desirable crunchy texture and chewing experience, while also providing (1) surface conditioning benefits resulting from altering the surface chemical characteristics of teeth and mucosal surfaces; (2) remarkable cleaning impression and positive mouthfeel effects for extended periods of time following use of the chewing gum; and (3) reduction of astringency conferred by metallic ion components without significantly reducing the efficacy of such metallic ions.

Gaffar's disclosure focuses on improving the anticalculus activity linear molecularly dehydrated polyphosphate salts comprising water soluble alkali metal hexametaphosphates by incorporating in the composition a water soluble alkali metal or ammonium synthetic anionic linear polymeric polycarboxylate to inhibit salivary hydrolysis of P--O--P bonds in the hexametaphosphates by phosphatase enzymes.

Chow et al. discloses a calcium phosphate-containing composition such as chewing gums, candies, confectioneries, toothpastes, dentifrices and gels containing non-toxic sparingly soluble calcium and phosphate causing the release of calcium and phosphate ions into the oral cavity gradually and persistently for a period no less than 5 minutes. The calcium salts may be a calcium phosphate salt such as  $\alpha$ -tricalcium phosphate, dicalcium phosphate anhydrous, dicalcium phosphate dihydrate, octacalcium phosphate or tetracalcium phosphate, thereby providing both calcium and phosphate ions. Or the sparingly-soluble calcium compound is a calcium salt of glycerophosphate, lactate, gluconate, or fumarate. The compositions are also formulated to contain a phosphate salt such as  $\text{Na}_2\text{HPO}_4$ ,  $\text{NaH}_2\text{PO}_4$ , and  $\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$  to supply phosphate ions and to maintain a desired pH. The calcium phosphate and other phosphate salts disclosed in Chow are provided having a particle size of less than 50  $\mu\text{m}$ , more preferably from about 1 to about 20  $\mu\text{m}$ . Contrary to the assertion in the Office Action, Chow does not disclose particulate phosphates having the recited particle size, i.e., from greater than 100  $\mu\text{m}$  (retained by a 0.1 mm mesh) to less than 2000  $\mu\text{m}$  (passes through a 2 mm mesh).

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It is submitted that there would be no motivation to combine the teachings of Chow relating to non-polymeric phosphate salts to the teachings of Gaffar, which relate to polymeric phosphates such as hexametaphosphate having anticalculus activity. Chow has no disclosure of polymeric phosphates or for that matter, non-polymeric phosphates having anticalculus activity. Therefore, no motivation is provided to use Chow's phosphates to substitute for Gaffar's polyphosphate as essential anticalculus agent. Assuming *arguendo* that there was motivation to incorporate Chow's phosphates into Gaffar's chewing gum, it would still not arrive at the present claimed composition having crunchy particulate polymeric materials such as polyphosphates having the specified particle size ranging from greater than 100 µm (retained by a 0.1 mm mesh) to less than 2000 µm (passes through a 2 mm mesh). Chow's phosphates have a much smaller particle size, i.e., less than 50 µm, more preferably from about 1 to about 20 µm and would thus pass through and not be retained by a 0.1 mm mesh. Importantly, Chow's smaller-sized phosphates would not provide the claimed crunchy texture to the composition.

Attention is further directed to the holding of the C.C.P.A in *In re Cofer* 53 C.C.P.A. 830 (January 13, 1966),

*"To be sure, whether a given chemical compound or composition has the same usefulness as closely related materials may be an important consideration in determining obviousness under 35 U.S.C.S. § 103. But it is only one consideration. Other factors which must be given weight in determining whether the subject matter as a whole would have been obvious include whether the prior art suggests the particular structure or form of the compound or composition as well as suitable methods of obtaining that structure or form. The new form of the compound set forth in the claims is as much a part of the "subject matter as a whole" to be compared with the prior art as are other properties of the material which make it useful."*

The rejection under U.S.C. 35 §103 of the *Cofer* claims to a chemical compound which is free-flowing and crystalline was reversed by the C.C.P.A. because there is no

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support in the record for the finding of the Examiner or the Board that the physical form (i.e., crystalline) of the claimed compound would have been obvious and further because insufficient weight was given to the various advantages derived from such crystalline form.

As in *Cofer*, Applicants submit that the cited references do not disclose or make obvious the specific physical form of the present polymeric surface active agents, being particles of a size ranging from greater than 100 µm to less than 2000 µm and having a specific solubility and the desirable results derived therefrom.

There is no recognition in Gaffar or in Chow of the desirability of providing a consumer-noticeable and desirable crunchy texture and dissolution properties to the chewing gum product and of changing the chemical surface characteristics of oral surfaces and thereby providing positive mouthfeel effects and cleaning impression. Absent such recognition, Gaffar taken with Chow could not have made obvious the present claimed compositions and methods using a polymeric surface active agent such as a polyphosphate in particulate form of specific particle size and solubility to provide these benefits as well as the additional benefit of reducing astringency conferred by metallic ions if present.

Applicants respectfully submit that the present claims are not obvious in view of Gaffar taken with Chow and the rejection under 35 U.S.C. §103(a) should be withdrawn.

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### CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish their invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented, withdrawal of the claims rejection under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph and under 35 U.S.C. §103(a), and allowance of all application claims are respectfully requested.

Respectfully submitted,

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